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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,920	07/29/2003	Lee R. Bolduc	HRT-0303CON	8124

2777 7590 03/29/2007  
PHILIP S. JOHNSON  
JOHNSON & JOHNSON  
ONE JOHNSON & JOHNSON PLAZA  
NEW BRUNSWICK, NJ 08933-7003

EXAMINER
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GETTMAN, CHRISTINA DANIELLE

ART UNIT	PAPER NUMBER
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3734

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/29/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/628,920

Applicant(s)

BOLDUC ET AL.

Examiner

Christina D. Gettman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 58-72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 70-72 is/are allowed.
- 6) ☒ Claim(s) 58-69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                                     |                                                                                         |
|-------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                         | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>07/22/2004</u> . | 6) <input type="checkbox"/> Other: _____                                                |

**DETAILED ACTION**

***Response to Amendment***

**CLAIMS 1-57 CANCELLED.**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 58-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gwathmey et al. (U.S. Patent No. 4,809,695) in view of Yoon (U.S. Patent No. 5,330,503). Gwathmey et al. disclose the invention substantially as claimed including a method of formed an anastomosis including the steps of providing a plurality of clips (col. 7, line 15-16) having a first end and a second end (ref. 120, Fig. 4), the clip having a first configuration (see Fig. 18) and a second configuration (see Fig. 19), passing the first end of each of the plurality of clips through an outer wall of the graft vessel (see Fig. 19; the clips must go through part of the outer wall of the graft vessel in order to form the anastomosis), positioning the first end of the clips through the opening and inner wall of the target vessel (Fig. 18; col. 7, line 32-34; when the surgeon makes the flange, the staple goes through the interior of the target vessel wall), passing at least a portion of the clip through the graft vessel (col. 7, line 34-39), permitting each of the clips to assume a second position to approximate the two vessels (see Fig. 19; col. 7, line 5-61), positioning and spacing the clips radially about the graft vessel (see Fig. 22), each

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of the plurality of clips being passed through the vessels separately (col. 7, line 1-4; col. 8, line 32-35), compressing the two vessels together when the clip is in the second configuration (see Fig. 19; when the staples are closed, the tissues are further compressed together), the ends of the clip crossing over one another (see Fig. 19; col. 7, line 64-65), each clip isothermally transforming from the first configuration to the second configuration (clips are pushed into the second configuration by the clip applier and jaws), each clip being restrained in the first configuration (col. 6, line 53-59), and releasing the clip from the first configuration with forceps (col. 7, line 57-63; the clip ends are pushed together around the tissue by jaws which allow the mid section of the clip to separate from the connector (ref. 53) in order for the clip to form the second configuration). Gwathmey et al. are silent on the material of the clip but do disclose that the clip must have the capability of being able to be bent into the looped configuration. Yoon teaches a clip made out of flexible coil (col. 7, line 53-54) for the purpose of bendability when forming the second configuration. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Gwathmey et al. with a clip made out of superelastic material in order to allow the clip to have the capability to be formed into a looped/crossed-over configuration as described in Gwathmey et al.

***Allowable Subject Matter***

Claims 70-72 are allowed.

The following is a statement of reasons for the indication of allowable subject matter: Claims 70-72 are allowed because the recited combination of elements of a

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method for performing anastomosis including providing a plurality of clips made of superelastic material, coupling each of the clips, passing each of the clips through a graft vessel and a target vessel, and permitting the clips to assume a second configuration wherein a plurality of clips coupled to a band that is further severed and removed from the clips is not found nor fairly taught in the prior art of record.

### ***Response to Arguments***

Applicant's arguments filed March 16, 2006 have been fully considered but they are not persuasive. Applicant argues that Gwathmey and Fujitsuka neither describe or suggest all of the steps of the amended claim 58 including, for example, the step of passing the first end of a clip through an inner wall of a target vessel while the clips are still in the first configuration. Applicant believes that both references do not pass the clip through the inner surface until the clip is in the second configuration. In view of the rejections made above, Examiner respectfully disagrees. Examiner also notes that the claims do not recite what the second figuration means other than when the clip is in the second configuration, the graft vessel and the target vessel are approximated, or brought together/abutted against one another.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina D. Gettman whose telephone number is 571-272-3128. The examiner can normally be reached on Monday-Friday 7:15 am to 3:45 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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CG  
  
Christina Gettman  
Art Unit 3734  
571-272-3128



MICHAEL J. HAYES  
SUPERVISORY PATENT EXAMINER